REMARKS

Claims 1-110 remain in the Application. No new subject matter has been added.

Applicant would like to acknowledge the Examiner's decision to allow Claims 48, 49 and 60. Further to the extensive discussion the Examiner had with Marcelo Sarkis and after reviewing the Examiner's Office Action, Applicant would like to clarify a few points:

1) At page 5, lines 12 and 13, the Examiner indicated that Mr. Sarkis questioned the patentability of the method of use claims as amended. Applicant would like to clarify that Mr. Sarkis was not questioning the patentability of the method of use claims but was asking the Examiner's position in respect of the method of use claims. Applicant does not want the sentence to be misconstrued as a concession that the patentability of the method of use claims is in question by the Applicant or Applicants' agent. The question of patentability was not being conceded. Mr. Sarkis was only questioning the Examiner's position. Applicant respectfully requests the Examiner to acknowledge this point in her next communication.

2) The Examiner has indicated that Claims 1-110 are provisionally rejected under the judicially created Doctrine of Double-Patenting over Claims 1-66, 110, 112-119 and 122-132 of co-pending Application No. 09/567,451. Furthermore, the Examiner has indicated that this is a provisional double-patenting rejection since the purported conflicting claims have not yet been patented. Applicant respectfully submits that Applicant will undertake to file a terminal disclaimer upon receiving an allowance of all the pending claims in this case over the prior art without agreeing that a terminal disclaimer is required.

ANTICIPATION

The Examiner has rejected Claims 1-15, 17, 19-37, 39, 43, and 63-78 under 35 U.S.C. 102(b) as being anticipated by EPA 856313 (hereinafter "EPA '313"). The Examiner states that EPA '313 discloses a once daily product wherein the release rates overlap those claimed by Applicant. Applicant respectfully submits that all the independent claims as amended in the present application includes the limitation of a neutral copolymer as the at least one water insoluble swellable polymer. EPA '313 does not teach nor suggest the use of a neutral copolymer. The Examiner states that Claim 8 of EPA '313 broadly teaches the use of copolymers of acrylic and methacrylic esters, which would include the use of a neutral copolymer as the water insoluble polymer. However, Applicant respectfully submits that this teaching in EPA '313 does not include a neutral copolymer. All of the Eudragit-type polymeric materials taught in EPA '313 are charged polymers. Applicant has provided below a table of the Eudragit-type polymers and their corresponding charges. This information would have been known to the skilled artisan at the time of filing of the EPA '313 application.

Name	Charge
Eudragit RL	Cationic [ammonium]
Eudragit RS	Cationic [ammonium]
Eudragit L	Anionic [Carboxyl]
Eudragit S	Anionic [Carboxyl]
Eudragit E	Cationic [Diethyl amino]
Eudragit RL 30D	Cationic [ammonium]
Eudragit L 30D	Anionic [Carboxyl]
Eudragit E 12.5	Cationic [Diethyl amino]
Eudragit RL 12.5	Cationic [ammonium]
Eudragit RS 12.5	Cationic [ammonium]

Given that all of the Eudragit type polymers taught in EPA '313 are charged, Applicant submits that the skilled artisan, having read EPA' 313 in its entirety would

not have deviated from the teachings of EPA '313 to use a neutral copolymer as there is no motivation provided by the teachings of EPA '313 to use a neutral copolymer.

The Examiner has recommended a side-by-side comparison of the EPA '313 formulation to that of Applicant's claimed formulation. Applicant has now compared pharmacokinetic parameters of the preparation as claimed in the instant application (currently marketed as Cardizem LA), which is limited to a neutral copolymer, to the product described in EPA '313 (see Tables 1 and 2 and Figures 1 and 2). EPA '313 is equivalent to US 5,002,776, which is listed in the FDA Orange Book for Cardizem CD. The pharmacokinetic data for Cardizem CD has been published in Thiffault et al. (previously submitted to the Examiner - should the Examiner require a copy of this reference, please advise):

Table 1

Parameters	Cardizem LA 360 mg		Cardizem CD 240 mg[a]	
	Day	Night	Day	Night
$AUC_{0-\tau}$	3691 ± 1449	4251 ± 1219	2008 ± 814	1754 ± 715
C_{max}	274.5 ± 149.0	290.9 ± 94.0	137.7 ± 48.6	127.6 ± 47.8
Plasma Fluctuation	118.9 ± 70.8	93.6 ± 29.5	112.5 ± 25.5	125.8 ± 31.2

a – data based on Thiffault article
$AUC_{0-\tau}$ = Steady-state area under the curve, τ = dosing interval = 24 hours

To normalize for the differences in dosage strength of the two diltiazem preparations, the above data is presented below in Table 2 as a Night/Day ratio:

Table 2

Parameters	Night/Day Ratio	
	Cardizem LA	Cardizem CD
AUC	1.15	0.874
C_{max}	1.06	0.927
Plasma Fluctuation	0.787	1.12

Table 1 shows the raw data for the various pertinent pharmacokinetic parameters. When the data in Table 1 is converted to Night/Day ratios of the pharmacokinetic parameters it is quite clear that the pharmacokinetics of LA is better than that of CD (Table 2). The LA formulation provides for a much higher bioavailability (both AUC and C_{max} are > than 1) and lower plasma fluctuation (< 1) during the night than CD.

Figure 1: Mean Steady-State Diltiazem Concentrations Following Administration of Cardizem LA 360 mg

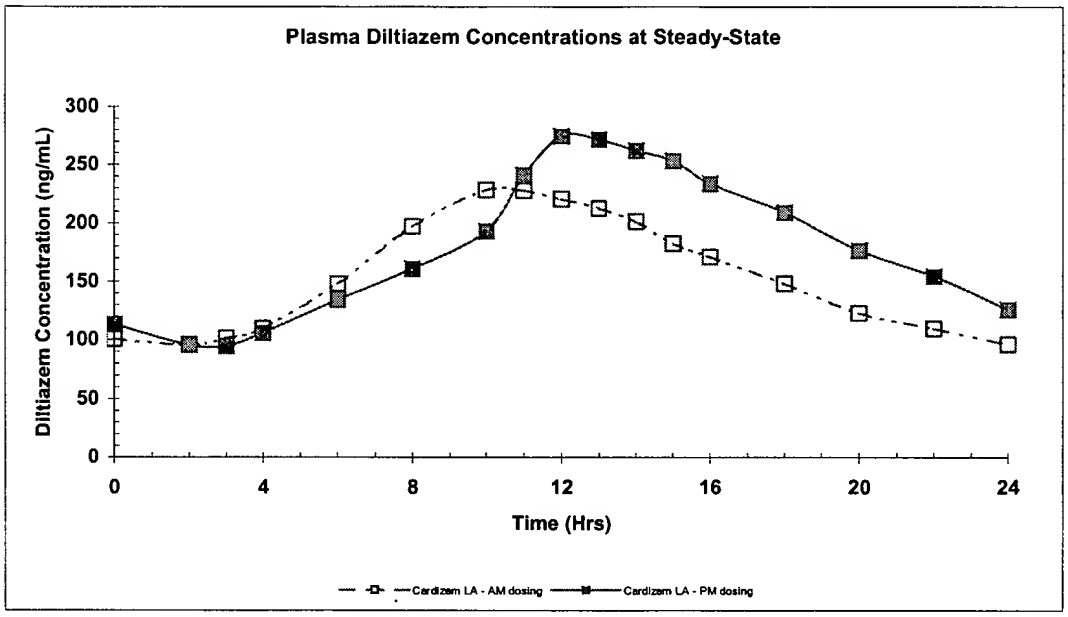
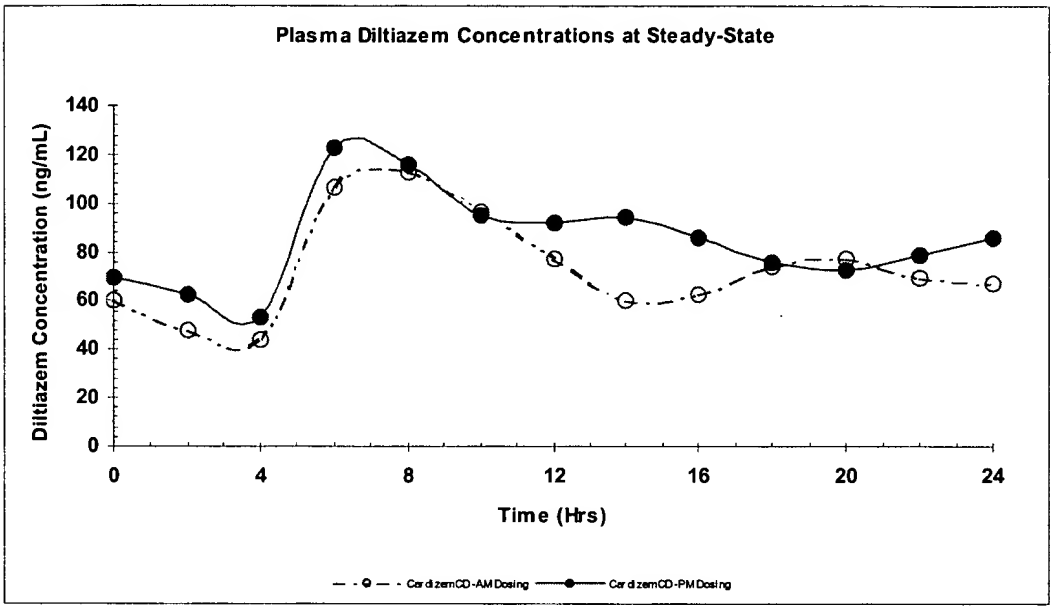


Figure 2: Mean Steady-State Diltiazem Concentrations Following Administration of Cardizem CD 240 mg



LA-PM vs. AM DOSING

Figure 1 together with Tables 1 and 2 demonstrate that:

1. When dosed in the evening, plasma diltiazem concentrations begins to rise at about 4 hrs after administration and peaks at about 11 hrs. Keeping in mind the fact that epidemiological studies have shown that the greatest incidence of heart problems and sudden cardiac death occur during the early morning waking hours when blood pressure is rising in response to the natural circadian rhythm, administering LA around 8-10 pm would result in diltiazem levels peaking during the critical early morning waking hours when the drug would be needed most,
2. A higher C_{max} is reached when dosed in the evening (see also Tables 1 and 2),
3. The bioavailability of diltiazem is higher when LA is dosed in the evening (see Tables 1 and 2, AUC Night/Day ratio >1). The higher

bioavailability of diltiazem from the LA formulation translates to higher plasma diltiazem concentrations, and

4. LA exhibits a lower plasma fluctuation when compared to CD (see Table 2).

CD PM vs. AM DOSING

Figure 2 together with Tables 1 and 2 show that:

1. CD when dosed at night begins to increase around 4 hrs after administration and peaks about 6 hrs after administration. Thus, dosing CD around 8-10 pm would result in diltiazem levels peaking much too early (around 2-4 am),
2. A lower C_{max} is reached when dosed in the evening compared to LA (almost half of LA, see Figure 2 and Tables 1 and 2, C_{max} Night/Day ratio is < 1),
3. A lower bioavailability is achieved when dosing in the evening compared to LA (see Tables 1 and 2, AUC Night/Day ratio is < 1), CD exhibits much higher plasma fluctuation and hence more adverse effects compared to LA (see Table 2).

The above data clearly show the unexpected results obtained by the instantly claimed invention, which comprises the use of a neutral copolymer, compared to the product described by EPA '313, which teaches the use of charged copolymers of acrylic and methacrylic acid ester polymers and neither teaches nor suggests the use of a neutral copolymer. Further, EPA '313 neither teaches nor suggests the night-time effect of administering its product on the bioavailability of diltiazem. This effect would not be inherent to the EPA '313 product as the pharmacokinetics of the product disclosed in EPA '313 is significantly different from the product as claimed in the instant invention as established by the data above. All of the unexpected

novel features of the instantly claimed invention result in a true chronotherapeutic formulation. Therefore, Applicants' invention clearly exhibits unexpected results.

Applicant respectfully submits that the Examiner has not pointed to any facts or evidence establishing that any acrylic acid and methacrylic ester will necessarily result in the product of the instantly claimed invention. Indeed, the data provided above, clearly demonstrates that not every acrylic and methacrylic ester will function to provide the beneficial release profile for diltiazem of the instantly claimed invention. Accordingly, Applicant respectfully submits that the teaching in EPA '313 of the use of "copolymer of acrylic acid and methacrylic esters" is not broad, is limited to copolymers of acrylic and methacrylic acid which are charged, and certainly does not include the use of a neutral copolymer.

The Examiner refers to the teaching of claim 8 of EPA '313. It is undeniable, however, that a "neutral copolymer" is not explicitly taught or suggested in EPA '313. Applicant respectfully submits, however, that the Examiner has construed the term "copolymer of acrylic and methacrylic ester" as inherently including a "neutral copolymer".

A fundamental rule of claim construction is that terms in a patent document are construed with the meaning with which they are presented in the patent document. Bell Atl. Network Servs., Inc. v. Covad Communications Group, Inc., 262 F.3d 1258, 1267-68 (Fed. Cir. 2001); Multiform Desiccants, Inc. v. Medzam, Ltd., 133 F.3d 1473, 1477 (Fed. Cir. 1998). Thus claims must be construed so as to be consistent with the specification, of which they are a part. Gen. Am. Transp. Corp. v. Cryo-Trans. Inc., 93 F.3d 766, 770 (Fed. Cir. 1996); Slimfold Mfg. Co. v. Kinkead Indus. Inc., 810 F.2d 1113, 1117 (Fed. Cir. 1987). In order to establish that a particular element is inherently disclosed by a reference, it must be established that the descriptive matter missing from the reference is necessarily present in the reference's disclosure, and

that persons of ordinary skill in the art would recognize the presence of that element. Id. at 745, 49 USPQ2d at 1950-51, citing Continental Can Co. v. Monsanto Co., 948 F.2d 1264, 1268, 20 USPQ2d 1746, 1749 (Fed. Cir. 1991). Inherency cannot, in law, be established by probabilities or possibilities. The fact that a specific result might occur from a certain set of circumstances is insufficient to establish inherency. Robertson, 169 F.3d at 745, 49 USPQ2d at 1951, citing Continental Can, 948 F.2d at 1269, 20 USPQ2d at 1749, citing In re Oelrich, 666 F.2d 578, 581, 212 USPQ 323, 326 (CCPA 1981).

In this instance, Applicant respectfully submits that the Examiner has not pointed to any facts or evidence establishing that any acrylic and methacrylic acid ester will necessarily result in the product of the instantly claimed invention. If EPA '313 meant to include "neutral copolymers" in its preparation, then substituting a charged copolymer of acrylic and methacrylic acid ester with a neutral copolymer would result in a substantially similar release profile of the diltiazem regardless of whether a neutral or charged copolymer is used to make the chronotherapeutic diltiazem preparations. However, the data presented above clearly demonstrates this not to be the case. The release profiles obtained when using a neutral copolymer, as in the instantly claimed application, and that obtained when using a charged copolymer are significantly different and clearly demonstrates that not every acrylic and methacrylic ester will function to provide the beneficial release profile for diltiazem of the instantly claimed invention. Therefore, Applicant respectfully submits that the teaching in EPA '313 of the use of "copolymer of acrylic acid and methacrylic esters" is limited to the teaching of charged copolymers of acrylic and methacrylic acid esters only, is not broad and certainly does not include the use of a neutral copolymer.

Applicant respectfully submits, the claims of the instant application are not anticipated by EP' 313.

Applicant respectfully submits that the Examiner must read EPA '313 without 20/20 hindsight. At the time of filing and the publication of EP '313, Applicant respectfully submits that "neutral copolymers", in one instance a neutral copolymer, of acrylic acid and methacrylic esters were known and available. However, it is clear to one skilled in the art that from reading EPA '313 in respect of all references to the copolymers therein, such person would conclude that all the polymers listed in EPA '313 include the charged forms available at that time except neutral copolymers. See at page 4, lines 41-42, 53-54; page 5, lines 4-18, 52-53; and page 6, lines 1-7 of EPA '313. The table of Eudragit-type polymers and their charges provided above in this response listing the polymers found in EPA '313 with their charge support same.

> "Rejection for anticipation or lack of novelty requires, as the first step in the inquiry, that all the elements of the claimed invention be described in a single reference."

In re Spada, 911 F.2d 705, 708, 15 USPQ2d 1655, 1657 (Fed. Cir. 1990), citing Richardson v. Suzuki Motor Co., 868 F.2d 1226, 1236, 9 USPQ2d 1913, 1920 (Fed. Cir. 1989).

The Examiner has not established that EPA '313 anticipates the claims in this application. The claims of the present invention require the at least one coating to have a neutral copolymer. EPA '313 discloses copolymers that are either anionic or cationic in nature, none more. The Examiner's statement of rejection with respect to EPA '313, Applicant respectfully submits fails to address the limitation in the claims of the at least one coating comprising a neutral copolymer.

Thus, Applicant respectfully submits, claims 1-15, 17, 19-37, 39, 43 and 63-78 are not anticipated by EPA '313. Reconsideration of the claims is respectfully requested.

OBVIOUSNESS – EPA ' 313

Claims 1-47, 50-59 and 61-110 of the instant invention have been rejected as being obvious in view of EPA 0 856 313 to Geoghegan *et al.* (EPA '313).

It is the Examiner's view that the skilled artisan, after having read EPA '313, would have been motivated to arrive at the instantly claimed invention through minimal experimentation, absent the presentation of some unexpected results by the Applicant. The Examiner has taken the position that the limitations of the instantly claimed invention are taught by EPA '313. In particular, it is the Examiner's opinion that the formulation disclosed in EPA '313 teaches a varied range of the amount of active ingredient, as well as the presence of additional additives, such as lubricants. The Examiner has also taken the position that the formulation disclosed in EPA '313 also releases the drug at the same rate as that claimed by Applicant. Therefore, it is the Examiner's position that these limitations do not render any unexpected results. It is the position of the Examiner that these are limitations, which would be routinely determined by one of ordinary skill through minimal experimentation, as being suitable, absent the presentation of some unexpected results.

Furthermore, it is the position of the Examiner that EPA '313 teaches the generic concept of the invention, as well as the suggestion to manipulate the formulation to result in varying dissolution rates and Cmax values. The Examiner further states that one of ordinary skill in the art would have been motivated to manipulate the formulation based on the specifics of the desired formulation. The expected result would be a successful pharmaceutical formulation. Therefore, this invention as a whole would have been, to the Examiner, *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Applicant submits that the copolymer of acrylic and methacrylic ester taught in claims 8 and 10 of EPA '313 does not include a neutral copolymer. All of the

Eudragit type polymeric materials taught in EPA '313 are charged polymers as already shown in the table above.

Applicant respectfully traverses the Examiner's rejection and requests that the Examiner refer to the test results of Table 1, Table 2, Figure 1 and Figure 2, as well as the summary of the test results provided above in respect of a comparison between Applicant's invention and that of EPA '313. The Examiner will clearly see that there was no motivation in EPA '313 as there was no appreciation of the problem, which is overcome with Applicant's invention, namely a true chronotherapeutic formulation.

Once again, the data provided above clearly show the unexpected results obtained by the instantly claimed invention, which comprises the use of a neutral copolymer, compared to the product described by EPA '313, which teaches the use of charged copolymers of acrylic and methacrylic acid ester polymers and neither teaches nor suggests the use of a neutral copolymer. EPA '313 also does not teach or suggest the night-time effect of administering its product on the bioavailability of diltiazem. Further, this effect would not be inherent to the EPA '313 product as the pharmacokinetics of the product disclosed in EPA '313 is significantly different from the product as claimed in the instant invention as established by the data above. All of the unexpected novel features of the instantly claimed invention result in a true chronotherapeutic formulation. Therefore, as already mentioned above, Applicants' invention clearly exhibits unexpected results.

Thus, EPA '313 does not render Applicant's invention obvious. Reconsideration is respectfully requested.

OBVIOUSNESS – WO '093

The Examiner has also rejected Claims 1-47, 50-59, and 61 and 62 under 35 U.S.C. 103(a) as being unpatentable over WO 93/00093 (hereinafter "WO '093"). The

Examiner states that WO '093 discloses an extended release galenical form of Diltiazem or a pharmaceutically acceptable salt, with a wetting agent, coated with a microporous membrane comprising at least a water soluble polymer and a pharmaceutically acceptable adjuvant. The Examiner further states that WO '093 teaches that the composition comprises beads containing between 120 and 480 mg of the active ingredient, with the wetting agent, and the beads are coated with the microporous membrane (p. 19, claim 1). It is the Examiner's position that WO '093 further teaches that the water soluble polymer or copolymer can include HPMC and Eudragit (p. 8, l. 21-28), and that WO '093 teaches that the following ingredients are included in the formulation: wetting agents such as fatty acid esters of saccharose (2-20%), microcrystalline cellulose (5-25%), polyvinylpurrolidone (1-15%), titanium oxide, surfactants such as tween, antifoaming agents, magnesium stearate, and talc (see pages 8-10).

Although the Examiner takes the position that WO '093 teaches a formulation for once daily administration, WO '093 does <u>not</u> teach that the formulation is suitable for evening dosing as will be clearly seen in the data provided below. The Examiner has conceded that WO '093 does <u>not</u> teach the rates of release as claimed by Applicants and neither is there i) a discussion of the rates of release after eight hours or ii) specific amounts of the ingredients.

The Examiner further states that it is her position that the specific amounts of ingredients which are not disclosed in WO '093 are limitations which would be routinely determined by one of ordinary skill in art through minimal experimentation, absent the presentation of some unexpected results. Applicant respectfully submits that this is not the case. Specifically, in WO '093 there was no appreciation of a chronotherapeutic formulation as such. There was no appreciation of the problem associated with the current Diltiazem formulations available and the solution, namely a true chronotherapeutic formulation. In determining obviousness,

Applicant respectfully submits, one needs to recognize the problem, see, for example, *Monarch Knitting Machine Corporation v. Solzer Morat GmbH*, 45 USPQ 2d (1977), 1981-1982 (Fed. Cir. 1998)

> "where the District Court's formulation of the problem confronting the '053 inventors presumes the solution to the problem - modification of the stem segment. Defining the problem in terms of its solution reveals improper hindsight in the selection of the prior art relevant to obviousness. See, EG In re Antal, 58 CCPA 1382 444 F.2d 1168, 1171-72, 170 USPQ, 285, 287-88 (CCPA 1971)."

Therefore, again, Applicant respectfully submits WO '093 does not render obvious Applicant's invention. This is clearly shown in the data below where pharmacokinetic parameters of the preparation as claimed in the instant application currently marketed as Cardizem LA, which is limited to a neutral copolymer to the product described in WO '093 (see Tables 3 and 4 and Figures 1 and 3). WO '093 is equivalent to US 5,529,791, which is listed in the FDA Orange Book for Tiazac. Tiazac is not a chronotherapeutic product as clearly spelled out in Figure 8 of Applicant's application.

Table 3

Parameters	Cardizem LA 360 mg		Tiazac 360 mg[b]	
	Day	Night	Day	Night
$AUC_{0-\tau}$	3691 ± 1449	4251 ± 1219	2870 ± 1005	2754 ± 810
C_{max}	274.5 ± 149.0	290.9 ± 94.0	243.2 ± 79.0	200.3 ± 59.1
Plasma Fluctuation	118.9 ± 70.8	93.6 ± 29.5	171.4 ± 43.8	144.8 ± 26.7

b – Data based on Bioclin Research Laboratories Analytical Report. Report is available should the Examiner request it.

$AUC_{0-\tau}$ = Steady-state area under the curve, τ = dosing interval = 24 hours

Table 4 below provides night/day ratio

Table 4		
Parameters	**Night/Day Ratio**	
	Cardizem LA	**Tiazac**
AUC	1.15	0.960
C_{max}	1.06	0.824
Plasma Fluctuation	0.787	0.845

Table 3 shows the raw data for the various pertinent pharmacokinetic parameters. When the data in Table 3 is converted to night/day ratios of the pharmacokinetic parameters, it is quite clear that the pharmacokinetics of LA is better than that of Tiazac (Table 4). The LA formulation provides for a much higher bioavailability, both area under the curve and Cmax are greater than 1 and lower plasma fluctuation during the night than Tiazac.

For ease of reference and comparison, Figure 1 is re-produced below:

Figure 1: Mean Steady-State Diltiazem Concentrations Following Administration of Cardizem LA 360 mg

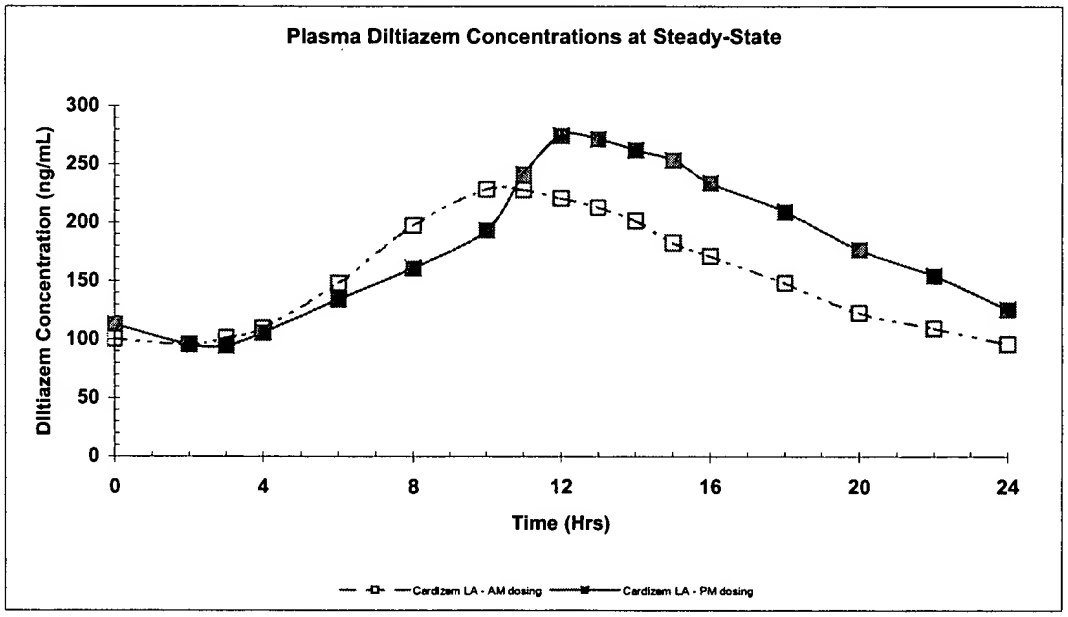
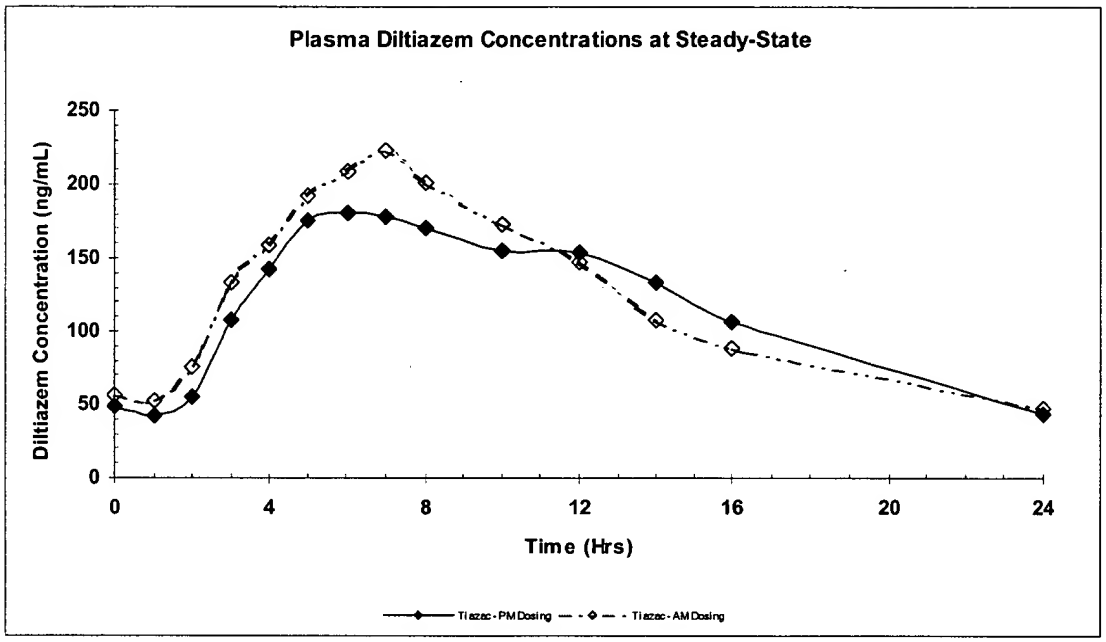


Figure 3: Mean Steady-State Diltiazem Concentrations Following Administration of Tiazac 360 mg



LA-PM vs. AM DOSING

Figure 1 together with Tables 3 and 4 demonstrate that:

1. When dosed in the evening, plasma diltiazem concentrations begins to rise at about 4 hrs after administration and peaks at about 11 hrs. Keeping in mind the fact that epidemiological studies have shown that the greatest incidence of heart problems and sudden cardiac death occur during the early morning waking hours when blood pressure is rising in response to the natural circadian rhythm, administering LA around 8-10 pm would result in diltiazem levels peaking during the critical early morning waking hours when the drug would be needed most,
2. A higher C_{max} is reached when dosed in the evening (see also Tables 3 and 4),
3. The bioavailability of diltiazem is higher when LA is dosed in the evening (see Tables 3 and 4, AUC Night/Day ratio >1). The higher

bioavailability of diltiazem from the LA formulation translates to higher plasma diltiazem concentrations, and

4. LA exhibits a lower plasma fluctuation when compared to Tiazac (see Table 4).

TIAZAC PM vs. AM DOSING

Figure 3 together with Tables 3 and 4 show that:

1. Tiazac when dosed at night begins to increase around 2 hrs after administration and peaks at about 6 hrs after administration. Thus, dosing Tiazac around 8-10 pm would result in diltiazem levels peaking much too early (around 2-4 am),
2. A lower Cmax is reached when dosed in the evening compared to LA (see Figure 3 and Tables 3 and 4, Cmax Night/Day ratio is <1),
3. A lower bioavailability is achieved when dosed in the evening compared to LA (see Tables 3 and 4, AUC Night/Day ratio is <1),
4. Tiazac exhibits a higher plasma fluctuation and hence more adverse effects compared to LA (see Table 4).

The above data clearly shows the unexpected results obtained by the instantly claimed invention, which comprises the use of a neutral copolymer compared to the product described by WO '093. WO '093 does not teach or suggest a night time effect of administering its product on the bioavailability of diltiazem. Further, this effect would not be inherent to the WO '093 product as the pharmacokinetics of the product disclosed in WO '093 is significantly different from the product as claimed in the instant invention as established by the data above. All of the unexpected novel features of the instantly claimed invention result in the true chronotherapeutic formulation. Therefore, Applicant's invention clearly exhibits unexpected results. Furthermore, the above comparison, Applicant respectfully submits, addresses the Examiner's concern that the previous data submitted regarding Tiazac was

concerning a 240 mg formulation and the data regarding Applicant's claimed formulation was based on a 300 mg capsule. Now, the comparison to Tiazac, as well as to the Applicant's formulation, are now based on the same dosage amount, thus satisfying the Examiner's request.

Given the facts provided above, Applicant respectfully submits that the Examiner has failed to establish a *prima facie* case for obviousness in view of EPA '313 and in view of WO '093. Again, the Applicant refers the Examiner to the data presented above showing the unexpected results obtained when a neutral copolymer is used.

Applicant respectfully reminds the Examiner that the criteria for obviousness determinations are well established in US Patent Law and have been set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 17-18, 148 USPQ 459, 467 (1966). To establish obviousness based on a combination of the elements disclosed in the prior art there must be some motivation suggested in their teaching of the desirability of making the specific combination that was made by the Applicant. See In re Kotzab, 217 F.3d 1365, 1370, 55 USPQ2d 1313, 1316 (Fed. Cir. 2000), citing In re Dance, 160 F.3d 1339, 1343, 48 USPQ2d 1635, 1637 (Fed. Cir. 1998) and In re Gordon, 733 F.2d 900, 902, 221 USPQ 1125, 1127 (Fed. Cir. 1984).

While the Examiner asserts that "One of ordinary skill in the art would have been motivated to manipulate the formulation based on the specifics of the desired formulation", the Examiner has not provided any analysis regarding how any one of the references should be modified to arrive at the claimed invention. Rather, the Examiner provides the conclusory statement that it would have been obvious to one of ordinary skill in the art at the time of the invention to create a controlled release formulation of diltiazem based on the teachings of EPA '313 or WO '093 with the reasonable expectation of producing a composition that would exhibit Applicants'

results which the Examiner states are not unexpected. As the Examiner has not, within a degree of specificity pointed to the relevant portion of the cited references which would have led the artisan of ordinary skill to arrive at Applicants' invention as claimed, Applicant respectfully submits that the Examiner has not established a *prima facie* case of obviousness.

The Examiner is also reminded of the decision of the BPAI Appeal No. 2001-1779, Application No. 09/398,898 where the Board concluded as Applicant has submitted above.

In view of the forgoing, Applicant submits that the claims are in condition for allowance and early reconsideration of the present application is respectfully requested subject to the judicially created double-patenting obviousness rejection.

If the Examiner has any questions, she is respectfully requested to contact Applicants' Agents, Ivor M. Hughes or Marcelo K. Sarkis at (905) 771-6414 collect at her convenience.

Respectfully submitted,

IVOR M. HUGHES

Ivor M. Hughes
Registration No. 27,759
Agent for the Applicant

Marcelo K. Sarkis
Registration No. 37,015
Agent for the Applicant

MKS*kdk

Enclosures

1. Petition for Extension of Time;
2. Check in the sum of $950.00 U.S.